2013 OK 93
IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

Terry Cline, in his official capacity as Oklahoma Commissioner of Health, Lyle Kelsey, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision, Catherine V. Taylor, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners,	)	FILED SUPREME COURT STATE OF OKLAHOMA OCT 29 2013 MICHAEL S. RICHIE CLERK OF THE APPELLATE COURTS
Petitioners,	)	Case No. 111,939
v.	)	
Oklahoma Coalition for Reproductive Justice, on behalf of itself and its Members and Nova Health Systems, d/b/a Reproductive Services, on behalf of itself, its staff, and its patients,	)	**FOR OFFICIAL PUBLICATION**
Respondents.	)	

CERTIFIED QUESTIONS OF LAW FROM THE SUPREME COURT OF THE UNITED STATES

¶ 0 On December 4, 2012, this Court issued a memorandum opinion, finding House Bill 1970, 2011 Okla. Sess. Laws 1276, facially unconstitutional pursuant to the U.S. Supreme Court's decision in Planned Parenthood v. Casey, 505 U.S. 833 (1992). See Okla. Coal. for Reprod. Justice v. Cline, 2012 OK 102, 292 P.3d 27. The Attorney General filed a Petition for Certiorari with the U.S. Supreme Court on March 4, 2013. On June 27, 2013, the U.S.

Supreme Court granted certiorari in the case and certified two questions of law to the Supreme Court of Oklahoma.

CERTIFIED QUESTIONS ANSWERED

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PER CURIAM

¶ 1 The Supreme Court of the United States certified two questions of Oklahoma law under the Revised Uniform Certification of Questions of Law Act, 20 O.S. 2011 §§ 1601–1611:

> Whether H.B. No. 1970, Section 1, Chapter 216, O.S.L. 2011 prohibits: (1) the use of misoprostol to induce abortions, including the use of misoprostol in conjunction with mifepristone according to a protocol approved by the Food and Drug Administration; and (2) the use of methotrexate to treat ectopic pregnancies.

We answer both certified questions in the affirmative.

Procedural Background

¶ 2 In May of 2011, the Governor signed House Bill 1970, 2011 Okla. Sess. Laws 1276, into law.[1] The Respondents challenged the bill in Oklahoma

[1] Section 1, Subsection C, of H.B. 1970 provides:

> C. No physician who provides RU-486 (mifeprislone) or any abortion-inducing drug shall knowingly or recklessly fail to provide or prescribe the RU-486 (mifepristone) or any abortion-inducing drug according to the protocol tested and authorized by the U.S. Food and Drug Administration and as authorized in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug.

Section 1, Subsection A, defines "abortion-inducing drug" as:

County District Court. The District Court found H.B. 1970 was unconstitutional and issued a permanent injunction, prohibiting enforcement of H.B. 1970. The Attorney General appealed the order and filed a Motion to Retain in this Court. We retained the case and issued a memorandum opinion on December 4, 2012, in Case No. 110,765, affirming the district court's decision. We found H.B. 1970 was facially unconstitutional pursuant to the U.S. Supreme Court's decision in Planned Parenthood v. Casey, 505 U.S. 833 (1992). See Okla. Coal. for Reprod. Justice v. Cline, 2012 OK 102, 292 P.3d 27. On January 15, 2013, the Chief Justice issued the mandate in Case No. 110,765.[2]

¶ 3 The Attorney General filed a Petition for Certiorari with the U.S. Supreme Court on March 4, 2013. The U.S. Supreme Court Clerk filed a letter in Case No. 110,765 on March 14, 2013, advising this Court that a petition for certiorari review of the order in Case No. 110,765 had been filed on March 4, 2013. The Attorney General has not asked this Court to suspend the effectiveness of mandate in Case No. 110,765.

> [A] medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child. This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents or diagnostic drugs;

H.B. 1970 was codified at 63 O.S. 2011 § 1-729a.

[2] See Mandate, Okla. Coal. for Reprod. Justice v. Cline, No. 110,765 (Jan. 15, 2013). This Court "can take judicial notice *of its own records* in litigation interconnected with a case before it." Robinson v. Texhoma Limestone, Inc., 2004 OK 50, ¶ 13, 100 P.3d 673, 677.

¶ 4 On June 27, 2013, the U.S. Supreme Court granted certiorari in the case and certified two questions of law to this Court. See Terry Cline et al. v. Okla. Coal. for Reprod. Justice et al., No. 12-1094 (June 27, 2013). Further proceedings in the U.S. Supreme Court were reserved "pending receipt of a response from the Supreme Court of Oklahoma." Id. The certified questions were filed in this Court on July 1, 2013, in Case No. 111,939. The briefs filed in the U.S. Supreme Court were included with the certification order. After the certified questions were filed, the Attorney General filed a request for briefing schedule. This Court entered a briefing schedule on July 16, 2013. Applications for amicus briefs were filed by several organizations, and this Court granted those applications on August 16, 2013. Briefing was completed on October 2, 2013.

This Court Has Jurisdiction to Answer the Certified Questions

¶ 5 Petitioners sought certiorari to the U.S. Supreme Court from Oklahoma Supreme Court Case No. 110,765, which has been mandated and is not before this Court at this time. Oklahoma Supreme Court Rule 1.16 permits a party to file a motion to suspend the effectiveness of mandate if the party contemplates the filing of a petition for certiorari in the U.S. Supreme Court and authorizes suspension of the effectiveness of the mandate until 1) expiration of time to file the petition; or 2) notice of final disposition by the U.S.

Supreme Court.[3] Until a party makes a request to suspend the mandate pursuant to Rule 1.16 in Case No. 110,765, or upon final disposition by the U.S. Supreme Court, this Court will not suspend or recall the mandate in Case No. 110,765.[4]

¶ 6 The jurisdictional basis for a majority of this Court's decisions is derived from the jurisdiction conferred upon the Court by Oklahoma Constitution Article VII, § 4.[5] This section vests five types of jurisdiction in the Supreme Court: (1) appellate jurisdiction over all civil matters; (2) jurisdiction to

[3] Okla. Sup. Ct. R. 1.16.

[4] Although the Attorney General's failure to move to suspend the effectiveness of mandate is not fatal to our exercise of jurisdiction in this case, litigants practicing before this Court must conform to the rules and procedures of this Court. The file also indicates that no one from the Attorney General's office has filed an entry of appearance in Case No. 111,939 as required by Oklahoma Supreme Court Rule 1.5, which provides that "[a]ll parties to any proceeding in the appellate courts shall immediately, but no later than filing the first document in the appellate court, file an Entry of Appearance on the forms set forth in Rule 1.301, by counsel or an unrepresented party representing himself or herself." Okla. Sup. Ct. R. 1.5. "When no counsel enters a formal appearance on behalf of an appellate party this Court possesses the discretion to list as counsel the lawyer who has signed and submitted a brief or motion for that party." State ex rel. Okla. Bd. of Medical Licensure and Supervision v. Pinaroc, 2002 OK 20, n.1, 46 P.3d 114, 116 n.1.

[5] The Oklahoma Constitution, Article VII, § 4 provides:

> The appellate jurisdiction of the Supreme Court shall be co-extensive with the State and shall extend to all cases at law and in equity; except that the Court of Criminal Appeals shall have exclusive appellate jurisdiction in criminal cases until otherwise provided by statute and in the event there is any conflict as to jurisdiction, the Supreme Court shall determine which court has jurisdiction and such determination shall be final. The original jurisdiction of the Supreme Court shall extend to a general superintendent control over all inferior courts and all Agencies, Commissions and Boards created by law. The Supreme Court, Court of Criminal Appeals, in criminal matters and all other appellate courts shall have power to issue, hear and determine writs of habeas corpus, mandamus, quo warranto, certiorari, prohibition and such other remedial writs as may be provided by law and may exercise such other and further jurisdiction as may be conferred by statute. Each of the Justices or Judges shall have power to issue writs of habeas corpus to any part of the State upon petition by or on behalf of any person held in actual custody and make such writs returnable before himself, or before the Supreme Court, other Appellate Courts, or before any District Court, or judge thereof in the State. The appellate and the original jurisdiction of the Supreme Court and all other appellate courts shall be invoked in the manner provided by law.

Okla. Const. art. VII, § 4.

determine whether the Court of Criminal Appeals or the Supreme Court has jurisdiction over a controversy; (3) superintending control jurisdiction; (4) jurisdiction to issue writs of habeas corpus, mandamus, quo warranto, certiorari, prohibition, and such other remedial writs as may be provided by law; and (5) further jurisdiction conferred by statute.[6]

¶ 7 This Court may also exercise jurisdiction that arises independent of Article VII, § 4, and one example of this occurs when the Court answers a certified question from a federal court. In Bonner v. Oklahoma Rock Corp., we said:

> This court needs no explicit grant of jurisdiction to answer certified questions from a federal court; such power comes from the United States Constitution's grant of state sovereignty. By answering a state-law question certified by a federal court, we may affect the outcome of federal litigation, *but it is the federal court who hears and decides the cause.* "Except in matters governed by the Federal Constitution or by Acts of Congress, the law to be applied in any case is the law of the state." Certification assures that federal courts are apprised of the *substantive norms of the Oklahoma legal system.*

1993 OK 131, n.3, 863 P.2d 1176, 1178, n.3 (citations omitted).

[6] See 20 O.S. 2011 § 1602.

H.B. 1970 prohibits the use of misoprostol to induce abortions, including the use of misoprostol in conjunction with mifepristone according to a protocol approved by the Food and Drug Administration and prohibits the use of methotrexate to treat ectopic pregnancies

¶ 8 The U.S. Supreme Court certified two questions of law under the Revised Uniform Certification of Questions of Law Act, 20 O.S. 2011 §§ 1601–1611:

> Whether H.B. No. 1970, Section 1, Chapter 216, O.S.L. 2011 prohibits: (1) the use of misoprostol to induce abortions, including the use of misoprostol in conjunction with mifepristone according to a protocol approved by the Food and Drug Administration; and (2) the use of methotrexate to treat ectopic pregnancies.

The certified questions are questions of statutory interpretation.[7] The meaning of statutory language presents a pure question of law. W.R. Allison Enters., Inc. v. Compsource Okla., 2013 OK 24, ¶ 10, 301 P.3d 407, 410. Unresolved questions of state law may be answered by this Court if certified questions are presented in accordance with the Revised Uniform Certification of Questions of Law Act, 20 O.S. 2011 §§ 1601–1611. Section 1602 outlines the discretionary power afforded this Court under the Act:

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[7] Curiously, although the Attorney General has not issued an opinion interpreting H.B. 1970, the Attorney General states:

> [I]t should not be overlooked that this interpretation comes from the Attorney General, whose opinion "is binding upon the state officials whom it affects." Thus, this interpretation of the law is not Petitioners' "best guess" as to how the law will be interpreted and enforced; it is in fact how it *will* be enforced.

Petitioners' Brief in Chief at 23, n.41 (citations omitted).

The Supreme Court of Oklahoma "alone has the power to authoritatively determine the validity or invalidity of a statute." State ex rel. York v. Turpen, 1984 OK 26, ¶ 10, 681 P.2d 763, 767 (emphasis added).

> The Supreme Court . . . may answer a question of law certified to it by a court of the United States . . . if the answer may be determinative of an issue in pending litigation in the certifying court and there is no controlling decision of the Supreme Court or Court of Criminal Appeals, constitutional provision, or statute of this state.

20 O.S. 2011 § 1602.

¶ 9 In 1996, a U.S. manufacturer filed a new drug application for mifepristone.[8] The FDA approved the application for mifepristone in 2000. According to mifepristone's FDA-approved final printed label, an informational document providing guidance about a drug's indications, precautions, and dosage, the protocol for administration of mifepristone for the termination of pregnancy requires three office visits by the patient.[9] During the first office visit, the patient is given 600 mg of mifepristone orally. Two days later, the patient returns to the office and is given 400 µg (0.4 mg) of misoprostol orally. Two weeks later, the patient returns to the office for a third visit to verify the procedure was successful. Mifepristone's FDA-approved label states mifepristone can be administered through forty-nine days of pregnancy.

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[8] "In answering a certified question, the Court does not presume facts outside those offered by the certification order. Although we will neither add nor delete facts, we may consider uncontested facts supported by the record." McClure v. ConocoPhillips Co., 2006 OK 42, n.3, 142 P.3d 390, 392, n.3. Although the record on appeal to the U.S. Supreme Court is not before this Court, the facts recited are not disputed by the parties. Additionally, neither party disputes that these facts are included in the record, and neither party has provided a citation to the record indicating evidence to the contrary exists.

[9] The FDA does not design or test the proposed protocol and does not conduct its own clinical trials; rather, FDA experts scrutinize submissions by the drug's sponsor, and other interested parties, concerning the safety and efficacy of the drug. See Petitioners' Brief in Chief at app. 2–3; see also Planned Parenthood v. Dewine, 696 F.3d 490, 495 (6th Cir. 2012).

¶ 10 After FDA approval of mifepristone, additional clinical trials led to the development of new protocols for administering mifepristone. The practice of providing approved medications using regimens different from that described in the medication's final printed label is known as an "off-label use," or an "evidence-based regimen." The FDA has stated that evidence-based regimens are common, permissible, and can be required by good medical practice.[10]

¶ 11 Evidence-based regimens for administering mifepristone vary from the protocol in mifepristone's FDA-approved label in three ways. First, the evidence-based regimens allow women to take one-third the dosage of mifepristone at the first office visit. Second, the evidence-based regimens allow a woman to self-administer the second drug, misoprostol, in the privacy of her own home rather than at a medical facility. Third, evidence-based regimens extend the effective use of mifepristone from forty-nine days to sixty-three days into the pregnancy.

¶ 12 Both the protocol in mifepristone's FDA-approved label and the evidence-based regimens require mifepristone be used *in conjunction with* misoprostol to induce an abortion. Misoprostol has not been approved by the

[10] Dewine, 696 F.3d at 496 ("'[I]t is standard medical practice in the United States for physicians to prescribe FDA-approved drugs in dosages and for medical indications that were not specifically approved—or even contemplated—by the FDA, particularly where the alternative use is supported by adequate study.'").

FDA for use in abortions but has been approved by the FDA to treat ulcers. The FDA-approved label for misoprostol is silent on abortion-related uses.

¶ 13 Although the most common evidence-based regimens involve some combination of mifepristone and misoprostol, other evidence-based regimens involve the use of methotrexate. Methotrexate is also a drug frequently used by physicians to terminate early ectopic pregnancies without surgery. Ectopic pregnancies pose grave health risks, and surgical intervention can result in serious complications, including future infertility, organ damage, and death. Methotrexate was approved by the FDA to treat neoplastic diseases, psoriasis, and rheumatoid arthritis. The FDA-approved label for methotrexate is silent on abortion-related uses.

¶ 14 In 2011, the Legislature passed H.B. 1970. Section 1, Subsection C, of H.B. 1970 provides:

> C. No physician who provides RU-486 (mifepristone) or any abortion-inducing drug shall knowingly or recklessly fail to provide or prescribe the RU-486 (mifepristone) or any abortion-inducing drug according to the protocol tested and authorized by the U.S. Food and Drug Administration and as authorized in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug.[11]

[11] Title 63 O.S. Supp. 2010 § 1-729a regulated the specific drug RU-486 (mifepristone) prior to the passage of H.B. 1970. Section 1-729a was originally enacted by Senate Bill 1902, 2010 Okla Sess. Laws 1086, and provided specific restrictions regarding the distribution and use of RU-486 (mifepristone). It required the prescribing physician to have certain qualifications and prescribe the medication under specific conditions, but it made no mention of drug labels and did not apply to other substances.

H.B. 1970 made several significant changes to § 1-729a. For example: 1) it extended the existing restrictions on RU-486 (mifepristone) to "any abortion-inducing drug" and defined that term to include "a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically

To determine the meaning of H.B. 1970, we first look to the plain language of the statute. W.R. Allison, 2013 OK 24, ¶ 14, 301 P.3d at 411. "The Legislature is presumed to have expressed its intent in the text of the statute." Id. The rules of statutory construction are employed "[o]nly where the legislative intent cannot be ascertained from the statutory language, *i.e.*, in cases of ambiguity or conflict." McClure, 2006 OK 42, ¶ 12, 142 P.3d at 395.

¶ 15 Three times in Subsection C the phrase "RU-486 (mifepristone) or any abortion-inducing drug" is used. The Legislature's use of the word "or" to separate the term "RU-486 (mifepristone)" from "any abortion-inducing drug" shows its intent to treat the terms as separate and distinct. In re J.L.M., 2005 OK 15, ¶ 7, 109 P.3d 336, 339 ("The Legislature's use of the disjunctive word 'or' indicates its intent that either the custodial parent alone (with whom the child was living), or both parents, may be ordered to pay restitution."); Corp. Comm'n v. Union Oil Co., 1979 OK 30, ¶ 8, 591 P.2d 711, 715 ("The use of the word 'or' to connect these phrases in [the statute] indicates that the grounds for relief connected thereby are disjunctive, and each is sufficient in itself to authorize the relief requested.").[12]

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diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child"; 2) it added a definition for "drug label" to essentially reference FDA-approved guidelines for use of medications; and 3) in addition to earlier restrictions, it altered § 1-729a to require that RU-486 (mifepristone) and any "abortion-inducing drug" be provided or prescribed only "according to the protocol tested and authorized by the U.S. Food and Drug Administration and as authorized in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug."

[12] See also Hedrick v. Virginia, 513 S.E.2d 634, 640 (Va. 1999) ("[T]he use of the disjunctive word 'or' . . . signifies the availability of alternative choices."); Resolution Trust Corp. v. United Trust Fund, Inc., 57 F.3d

¶ 16 Therefore, under H.B. 1970 if a physician wishes to provide or prescribe RU-486 (mifepristone), the physician must provide or prescribe RU-486 (mifepristone) according to the FDA-approved label for *RU-486 (mifepristone)*. If a physician wishes to provide or prescribe any abortion-inducing drug, the physician must provide or prescribe the abortion-inducing drug according to the FDA-approved label for *that abortion-inducing drug*.

¶ 17 Abortion-inducing drug is defined in Section 1, Subsection A, of H.B. 1970 as:

> a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child. This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents or diagnostic drugs;

Misoprostol, when used in either the protocol described in the FDA-approved label for mifepristone or an evidence-based regimen, is an abortion-inducing drug as defined by subsection A because it is prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with

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1025, 1033 (11th Cir. 1995) ("[T]he disjunctive 'or' gives independent meaning to the words it separates."); Knutzen v. Eben Ezer Lutheran Housing Ctr., 815 F.2d 1343, 1349 (10th Cir. 1987) ("[T]he use of a disjunctive in a statute and regulations indicates that alternatives were intended."); Azure v. Morton, 514 F.2d 897, 900 (9th Cir. 1975) ("As a general rule, the use of a disjunctive in a statute indicates alternatives and requires that they be treated separately.").

knowledge that the termination shall with reasonable likelihood cause the death of the unborn child. Similarly, methotrexate, when used either in an evidence-based regimen or to treat ectopic pregnancies, is an abortion-inducing drug as defined by subsection A because it too is prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child.

¶ 18 The Attorney General argues that 63 O.S. 2011 § 1-730(A)(1) of the Public Health Code defines the term "abortion" to exclude the termination of ectopic pregnancies, so methotrexate can still be used off-label to treat ectopic pregnancies.[13] *But the operative term in H.B. 1970 is not the term "abortion," but rather the new, separately defined term "abortion-inducing drug."* The Legislature could have defined abortion-inducing drug to mean a medicine prescribed with the intent of causing an abortion. It did not. Instead, it defined it as a drug prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn

[13] Section 1-730(A)(1) provides:

> "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device intentionally to terminate the pregnancy of a female known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to remove an ectopic pregnancy, or to remove a dead unborn child who died as the result of a spontaneous miscarriage, accidental trauma, or a criminal assault on the pregnant female or her unborn child.

63 O.S. 2011 § 1-730(A)(1).

child. The fact that the Legislature excludes ectopic pregnancies from the definition of abortion in § 1-730(A)(1), yet defines "abortion-inducing drug" without incorporating § 1-730(A)(1) or including similarly exclusionary language indicates the Legislature intended to ban the off-label use of methotrexate, including its use in the treatment of ectopic pregnancies.

¶ 19 The Attorney General states that "[w]hile the most common off-label protocols involve some combination of [mifepristone] and misoprostol, *other off-label protocols involve the use of methotrexate followed by misoprostol, and others yet involve the use of just misoprostol or just methotrexate.*" Petitioners' Brief in Chief at 9, n.18 (emphasis added). The Legislature specifically referenced both misoprostol and methotrexate in the definition of an abortion-inducing drug: "This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate." We find that both misoprostol and methotrexate are abortion-inducing drugs as the term is used in Subsection A; therefore, under the plain language of Subsection C of the statute, the off-label use of both misoprostol and methotrexate is prohibited.[14]

[14] We find no merit to the Attorney General's argument that an ectopic pregnancy is not a "true 'pregnancy,'" so methotrexate can still be used off-label to treat ectopic pregnancies. Petitioners' Brief in Chief at 22. Title 63 O.S. 2011 § 1-730(A)(4) defines an "unborn child" as the "unborn offspring of human beings from the moment of conception, through pregnancy, and until live birth including the human conceptus, zygote, morula, blastocyst, embryo and fetus." And 63 O.S. 2011 § 1-730(A)(7) defines "conception" as "fertilization of the ovum of a female individual by the sperm of a male individual." Further

¶ 20 FDA-approved labeling is "not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient."[15] In an often-cited bulletin specifically addressing the use of approved drugs for unlabeled indications, the FDA stated:

> The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.
>
> The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigation.

FDA Drug Bulletin 12:4-5, 1982.[16]

¶ 21 As Respondents correctly point out, and as the FDA recognizes, human progress is not static: medical research and advances do not stop upon a particular drug's approval by the FDA. Researchers continue to perform

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discrediting this argument is the fact that the Legislature believed an ectopic pregnancy was a pregnancy having excluded the termination of ectopic pregnancies from the definition of "abortion" in 63 O.S. 2011 § 1-730(A)(1).

[15] Weaver v. Reagan, 886 F.2d 194, 198 (8th Cir. 1989).

[16] See also 59 Fed.Reg. 59,820, 59,821 (Nov. 18, 1994).

clinical trials, doctors continue to gain experience, and widespread use of a particular treatment allows the medical community to collect data about side effects, alternative doses, and potential new uses for treatments. Ninety-six percent of medication abortions in the United States are now provided according to a regimen different from the one described in mifepristone's FDA-approved label.[17] At the clinic operated by Respondent Reproductive Services, an evidence-based regimen for administering mifepristone is the most prevalent method for terminating early pregnancies, accounting for two-thirds of all abortions performed by the clinic, and the physicians at Reproductive Services have concluded that the protocol in the mifepristone FDA-approved label likely no longer meets the standard of care.[18] Both the American College of Obstetricians and Gynecologists and the World Health Organization have endorsed these alternate regimens as safer and more effective than the now-outdated regimen provided for in mifepristone's FDA-approved label.[19] "Good medical practice and the best interests of the patient

[17] Respondents' Answer Brief at 7 (citing R. on Appeal, Tab 14, App. 4, ¶¶ 21–24). Neither side in this cause disputes that when the FDA originally approved mifepristone, it did so under a regulatory provision known as Subpart H, which allows the FDA to restrict distribution of an approved drug by its sponsor to ensure safe use. See 21 C.F.R. § 314.520. Although the FDA required mifepristone's sponsor to distribute the drug only under conditions where it would be provided by or under the supervision of a physician who was able to meet certain criteria, the FDA did not go so far as to require that administering physicians utilize mifepristone according only to the protocol described in the FDA-approved label.

[18] Respondents' Answer Brief at 8 (citing R. on Appeal, Tab 14, App. 7, ¶¶ 9, 14–15 21).

[19] Respondents' Answer Brief at 7 (citing R. on Appeal, Tab 14, App. 4, Ex. B at 2).

require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment."[20]

¶ 22 In other areas of the law, the Oklahoma Legislature has recognized the importance of allowing physicians to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling. Title 59 O.S. 2011 § 509(16) provides that unprofessional conduct for physicians includes, among other criteria:

> Prescribing, dispensing or administering of controlled substances or narcotic drugs in excess of the amount considered **good medical practice**, or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standards.

59 O.S. 2011 § 509(16) (emphasis added).

While § 509(16) requires physicians only dispense certain drugs in amounts considered good medical practice, nowhere does it globally require physicians to dispense those drugs in accordance with their FDA-approved labels.

¶ 23 Title 63 O.S. 2011 § 1-2604 prevents health insurers from denying coverage for prescription drugs for cancer treatment merely because their use in the treatment of cancer or study of oncology is off-label. It provides:

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[20] United States Food and Drug Administration, Regulatory Information: "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

> **No individual policy of accident and health insurance issued which provides coverage for prescription drugs**, nor any group blanket policy of accident and health insurance issued which provides coverage for prescription drugs **shall exclude coverage of prescription drugs for cancer treatment or the study of oncology because the off-label use of such prescription drug has not been approved by the Federal Food and Drug Administration for that indication** in one of the standard reference compendia, as defined in paragraph (d) of Section 1-1401 of Title 63 of the Oklahoma Statutes.
>
> Any coverage of a prescription drug required by this section shall also include provisions for coverage of **medically necessary** services associated with the administration of the prescription drug. . . .

63 O.S. 2011 § 1-2604 (emphasis added).

¶ 24 Title 63 O.S. 2011 §§ 5030.1–5030.5 provide authorization and guidelines for the Medicaid Drug Utilization Review Board. The board is charged to:

> develop and recommend to the Oklahoma Health Care Authority Board a retrospective and prospective drug utilization review program for medical outpatient drugs to **ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.**

63 O.S. 2011 § 5030.4(1) (emphasis added).

Nowhere in §§ 5030.1–5030.5, however, is the board constrained by uses authorized in the FDA-approved labels for prescription drugs in making its determinations. Instead, the statute uses the term "medically necessary" in deference to the knowledge and experience of physicians exercised in the practice of medicine.

¶ 25 In contrast to the deference physicians receive regarding treatment decisions in almost all other areas of medicine, H.B. 1970 requires a physician to provide or prescribe mifepristone, misoprostol, and methotrexate according only to their respective FDA-approved drug labels.[21] It is undisputed that the FDA-approved label for mifepristone requires a dosage level no longer considered medically necessary. It is also undisputed that misoprostol has not been FDA-approved for abortion-related uses, and methotrexate has not been approved for either abortion-related uses or for treating ectopic pregnancies. The use of misoprostol in the protocol described in the mifepristone FDA-approved label is an off-label use prohibited by the terms of H.B. 1970, and the use of methotrexate in treating ectopic pregnancies is an off-label use also prohibited by H.B. 1970. **H.B. 1970 effectively bans all medication abortions.**

Conclusion

¶ 26 The role of the physician is to heal the sick and the injured, and physicians are required to undergo rigorous training to develop the required knowledge and experience to perform that role well. Physicians must inform their patient of the risks involved in any treatment, and together with the patient, must determine the best course of treatment. Part of the Hippocratic

[21] Abortion is the only area of medicine where it appears the Oklahoma Legislature has seen fit to restrict a physician's use of certain practices. See also 63 O.S. 2011 § 1-745.3; 63 O.S. 2011 § 1-745.5; 63 O.S. 2011 § 1-745.5(A).

Oath requires Physicians to "follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."[22]

¶ 27 When the district court originally found H.B. 1970 unconstitutional, it correctly concluded that:

> [t]he Act's restriction of the use of the drug RU-486 or "any other abortion inducing drug, medicine or other substance" in the manner and to the regimen set forth in the medication FPL when used for abortion is **so completely at odds with the standard that governs the practice of medicine** that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do.

Okla. Coal. for Repro. Justice v. Cline, No. CV-2011-1722, slip op., ¶ 7 (Dist. Ct. Okla. Cnty. May 11, 2012) (emphasis added). The plain language of the statute and the manner in which H.B. 1970 restricts the long-respected medical discretion of physicians in the specific context of abortion compels an affirmative answer to both of the questions asked, a position entirely consistent with our decision to affirm the ruling of the district court: **H.B. 1970 prohibits the use of misoprostol to induce abortions, including the use of misoprostol in conjunction with mifepristone according to a protocol approved by the Food and Drug Administration and prohibits the use of methotrexate to treat ectopic pregnancies.**

[22] Grant H. Morris, Dissing Disclosure: Just What the Doctor Ordered, 44 Ariz. L. Rev. 313 (2002) (quoting 20 Encyclopedia Americana 217 (int'l ed., deluxe libr. ed. 1993)).

CERTIFIED QUESTIONS ANSWERED

¶ 28 REIF, V.C.J., KAUGER, WINCHESTER, EDMONDSON, TAYLOR, COMBS and GURICH, JJ., concur.

¶ 29 COLBERT, C.J. and WATT, J., not voting.